K112196

510(k) Summary

SEP 14 2011

Submitter:
Dalim SurgNET Co.
Du Pyo Hong
C-308, High Tech Venture, 647-26
Deungchon-dong, Gangseo-gu,
Seoul 157-030, Korea
Phone: 82-2-3663-6669
Fax: 82-2-2668-6669

Official Correspondent:
Kodent Inc.
April Lee
325 N Puente St. Unit B
Brea, CA 92821
Email: kodentinc@gmail.com
Phone: 714-525-0114
Fax: 714-525-0116

Device Information
Trade Name: OCTO™ Port
Common Name: Laparoscopic Accessory
Classification Name: Endoscope and accessories
Product Code: OTJ
Regulation Number: 21 CFR 876.1500
Date of Submission: 7/25/2011

Indications for Use

The OCTO™ Port is intended to use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery.

Device Description & Technological Characteristics

The purpose of the device modification is to pursue the variety of products for surgeon's preference. Since the submission of the traditional 510(k), K100045, a number of additional non-significant modifications were made to the parent OCTO™ as follow:

- The color of the device is changed from light blue to blue to upgrade a brand image.
- The thickness of bottom ring of wound retractor is changed to make easy insertion into incision.
- The thickness of silicon around the top ring of wound retractor is changed to make easy retraction.
- The height of wound retractor has been lengthened to be used in obese patients.

- The gas valve was added to OT501S2, whereas the predicate device, OT501S, did not have gas valve
- The port cap is made to be rotated in 360 degrees due to the preference of users.
- The location of gas valve is changed to give more spaces for instruments during the surgery.
- The gas valve lever is loosened to make easy to control.
- The connection notches are attached on the port cap to make easy attachment and detachment of the port cap from wound retractor.
- The outer part of retractor is modified to be easily connected from the port cap by snapping.
- A silicone protector is added due to the preference of users.
- The arrangement and size of ports are changed to give wider range of ports.
- The heights of the ports are changed to give more spaces between instruments
- 12mm universal sealing is modified to make easy to insert clippers and other instruments.

The modified system has the same intended use and fundamental scientific technology as the previously-cleared system, OCTO™.

The OCTO™ Port is a sterile, disposable laparoscopic instrument port which retracts a small abdominal incision to allow multiple laparoscopic instruments to pass through to the abdomen.

Materials:

Wound retractor, remover, sealing, gas pipe were made of Silicon Rubber compound. Upper Frame, lower frame, port cap and the port were made of Acrylonitrile, Butadience, and Styrene co-polymer. Gas valve was made of polycarbonate.

Performance testing (Bench):

The testing scope for Bench Test was selected to include appearance inspection, dimension test, pressure leak test, tensile strength test, pressure injection test, instrument insertion/removal test, insertion test, fixation test, leak resistance, cannula insertion and removal evaluation, device compatibility, one handed use, retractor removal test and insufflations tube fixation forces maintain pneumoperitomeum.

Performance testing (Animal):

Since the mechanism of the device, the material used on the device, and the instruction of using the device are identical and consistent with the previously submitted models, no additional animal testing was performed.

Biocompatibility Testing:

Since the mechanism of the device, the material used on the device, and the instruction of using the device are identical and consistent with the previously submitted models, no additional biocompatibility testing was performed.

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

The name of the device: OCTO™

510(k) Number: K100045

Comparison to Predicate Devices:

The comparisons have established that the subject of OCTO™Port is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to other predicate device of the type currently marketed in the U.S.

Conclusion:

Based on the provided information in this premarket notification, it can be concluded that the subject device is substantial equivalent to the predicate devices and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dalim SurgNET Co.
% Kodent, Inc.
Ms. April Lee
325 N Puente Street, Unit B
Brea, California 92821

SEP 14 2011

Re: K112196
Trade/Device Name: OCTO™ Port
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OTJ
Dated: August 25, 2011
Received: August 29, 2011

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112196

Indication for Use

510(K) Number (if known): K112196

Device Name: OCTO™Port

Indication for Use:

The OCTO™ Port is intended to use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery.

Prescription Use _____x_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112196